US ERA ARCHIVE DOCUMENT

DATA EVAUATION RECORD

1. CHEMICAL: Metolachlor

2. FORMULATION: Technical

3. <u>CITATION</u>: Bathe, R. (1973) Acute Oral LD₅₀ of Technical CGA-24705 in the Rat: Project No. Siss 2979. Received September

in the Rat: Project No. Siss 2979. Received September 26, 1974 under 5G1553. (Unpublished report prepared by CIBA-GEIGY Ltd., Basle, Switzerland; CDL: 112840-A)

4. TRADE SECRET CLAIM: Yes

5. REASON FOR REVIEW: Generic Standard for Metolachlor

6. REVIEWED BY: W. Thomas Edwards

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7. DATA OF REVIEW: January 20, 1978

8. TEST TYPE: Acute Oral Toxicity Study

- A. Materials and Methods: Spraque-Dawley albino rats were used. Metolachlor was diluted at 20, 30 and 50% with 2% carboxymethylcellulose and administered by oral intubation. The males and females were segregated and housed in Macrolon cages (Type 3) in groups of 5 in a room kept at a constant temperature of 22 + 1 °C and relative humidity of approximately 50%. They received water and food (NAFAG, Gossau SG, rat food) ad libitum. The rats were starved during one night before starting the treatment.
- B. Reported Results:

vose	NO.		Death within							
mg/kg	Animals		1	1 hr.		24 hrs.		hrs.	7 days	
	M	E	M	F	M	F	M	E	М	F
1670	5	5	0	0	1	1	1	1	1	1
2150	5	5	. 0	0 .	2	1	2	1	2	1
2780	5	5 ,	0	0	1	4	1	4	1	4
4640	5	5	3	2	5	5	5	5	5_	5

The acute oral LD $_{50}$ in rats was estimated to be 2780 with 95% confidence limits of 2180-3545 mg/kg by method of Litchfield and Wilcoxon (1949)

Within 2 hours after treatment the rats in all dosage groups showed sedation, dyspnea, exophthalmus, curved position, trismus, tonic-clonic muscle spasms and ruffled fur. Those symptoms became more accentuated as the dose was increased.

The surviving animals had recovered within 3 to 5 days. They were killed and autopsied after an observation period of 7 days.

Gross autopsy revealed no substance related organ changes.

- C. Discussion: Animals were observed for only 7 days after dosing. Nevertheless, since no animals died after the second day and a general remission of symptoms was reported, it does not seem necessary to repeat this study because of short observation period.
- D. Conclusion: This study is adequate to meet current requirements and indicates the oral LD $_{\rm 50}$ for both males and females is approximatley 2780 mg/kg.